

Remarks

Claims 17, 18, and 21 have been amended. Claims 23, 24 and 25 have been added. The amendments to the claims are fully supported by the specification as filed. No new matter has been added by way of these amendments.

The Applicants acknowledge with appreciation the indication that claims 18 and 21 would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims. Claims 18 and 21 have been rewritten in accordance with the Examiner's suggestions and are now believed to be in a condition for allowance. Claim 23 has been added and contains additional allowable subject matter. Claim 23 depends from claim 18 and is believed to be allowable at least for the reason that it depends from an allowable claim.

Independent claim 17 has been amended to clarify that each of the two clips set forth in the claim has two end points and that the end points of each individual clip are separated when a clip is in its open configuration. Support for this amendment can be found throughout the Specification and particularly at Page 4 line 27 – Page 5 line 6 and Page 8 lines 16 – 27.

Claim Rejections Under 35 U.S.C. §102(b)

A determination of anticipation under 35 U.S.C. §102 requires a finding that each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. MPEP §2131.

Claim 17:

Claim 17 was rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,374,268 (Sander). Reconsideration of this rejection is respectfully requested.

Sander discloses a device for repairing torn tissue or muscle such as the meniscus of the knee. The device consists of a pair of needles (12) detachably secured to a pair of barbed anchor members (14). The needles are secured to the barbed anchors by way of adhesives, swaging, crimping or a quick-release connection. (Col. 2 lines 26-30; Col. 3 lines 63-65). The anchoring members are joined by a suture (16), which together with the anchors “serve to maintain the tear at close approximation” (Col. 2, lines 64-65).

Contrary to the Examiner’s assertion, Sander’s anchor members (14) are not clips. The anchor members “essentially comprise absorbable rods having outwardly projecting barbs...the barbs are provided to anchor the device in the tissue.” Col. 2 lines 21-23; Col. 2 lines 39-40. Additionally, the anchor members are not “held in an open configuration” as the Applicants’ claim sets forth. Sander does not disclose the anchor members as having open or closed configurations nor does Sander disclose anchor members with the ability to assume a configuration whereby the end point of an individual anchor member tends to move with respect to the other end point of that same anchor member. Rather, the anchor members of Sander are anchoring members “which are constructed of a bioresorbable material” and “are linked by a flexible material”. The “flexible material allows for movement of anchoring members *with respect to one another.*” (Col. 3 lines 47-58). Thus, the anchor members of Sander are disclosed as moving only with respect to one another and therefore are not clips having open and closed configurations. An anchor member of Sander does not tend to return to a naturally closed configuration by reducing distance between anchor member end points. Since Sander fails to disclose the clip assembly of the present invention withdrawal of the rejection of the claims as being anticipated by Sander is respectfully requested.

Applicants respectfully disagree with the Examiner that the statement “tending to return to a naturally closed configuration by reducing distance between said end points when the clip is in said open configuration” is a statement of intended use. According to MPEP §2111.02 II, whether a statement is one of intended use is an inquiry limited to a

claim preamble. To characterize the phrase in claim 17 as a statement of intended use is error and is contradictory to the MPEP guidelines for examination. Furthermore, the phrase in claim 17 sets forth a characteristic of the clips. Therefore, Applicants respectfully request the Examiner to withdraw the characterization of that portion of claim 17 as being a statement of intended use.

Claims 20 and 22:

Claims 20 and 22 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,002,563 (Pyka). Reconsideration of this rejection is respectfully requested.

Pyka discloses a suture and method for suturing a wound defined by tissue edges, the method comprising inserting a suture member through tissue adjacent the tissue edges defining the wound and into position for the member to recover towards a first suturing loop shape whereby the member draws and holds the tissue edges of the wound together. Col. 3 lines 6-17.

In the rejection of independent claim 20, the Examiner has failed to find each and every element as set forth in Applicants' claims. Indeed, Pyka neither inherently nor expressly discloses each and every element as set forth in Applicants' claim. Independent claim 20 provides in part a clip assembly "which comprises *two clips* each having two end points ... *two tissue penetrating needles* each connected to one of said two end points of a corresponding one of said two clips through a flexible member, *and a flexible connector connecting the other end points of said two clips together*" (emphasis added). Pyka does not disclose two clips connected to two tissue penetrating needles, nor does Pyka disclose two clips connected by a flexible member to one another, nor has the Examiner advanced that Pyka contains any such disclosure. Furthermore, Pyka does not disclose "penetrating and completely pulling one of the needles through a tissue part and penetrating and completely pulling the other of the needles through an adjacent tissue

part while said clips are each in said open configuration” and “pulling the needles until each of said clips is hooked to a corresponding one of the tissue parts; and allowing said clips to start to return to said naturally closed configuration, whereby said two tissue parts are held together by said flexible connector stretched between said clips.” Pyka fails to disclose a flexible connector stretched between two clips which thereby holds tissue parts together and the Examiner has failed to find that Pyka discloses any such element. If the Examiner believes that Pyka contains such a disclosure, the Applicants request that the Examiner clearly indicate where in the cited reference the elements are disclosed. Independent claim 20 and claim 22 which depends therefrom are allowable for at least the reasons presented herein. Therefore, Applicants respectfully request the Examiner to withdraw the rejection based upon Pyka.

Claim Rejections Under 35 U.S.C. §103(a)

Claim 19 was rejected under 35 U.S.C. §103(a) as being unpatentable over Sander in view of U.S. Patent No. 5,171,252 (Friedland). The Examiner advanced that it would have been obvious to a person of ordinary skill in the art to modify the clips disclosed by Sander to be made from shape memory metal as taught by Friedland and that such a modification would allow a change in the clamping force as the state of the metal is changed.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, the art must provide a reasonable expectation of success. Third, the prior art reference must teach or suggest all the claim limitations. MPEP § 2143. In addition, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727. Also, in the Examination

Guidelines for Determining Obviousness in view of the KSR decision, the USPTO has noted that the key to supporting any rejection under §103 is the *clear articulation of the reasons(s)* why the claimed invention would have been obvious. Indeed, the Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. §103 *should be made explicit*. Thus, it remains necessary to identify some reason that would have led a person of ordinary skill in the art to modify the teachings of a reference in a particular manner in order to establish *prima facie* obviousness.

Applicants respectfully submit that the Examiner has neither articulated nor made explicit either reasons or factors which would have led a person of ordinary skill in the art to modify Sander to be made of a shape memory alloy. First, Sander does not disclose or suggest clips and there is no suggestion in Sander or Friedland to modify the Sander suture and anchoring member device to be made of a shape memory alloy. In the §102(a) rejection based upon Sander, the Examiner advanced that the anchor members of Sander are clips. No reason has been advanced which would lead one to modify the barbed anchor members of Sander such that the anchor members be made from a shape memory metal. Furthermore, the Examiner's reasoning that since "Friedland teaches anchors with barbs or clips that are made from shape memory material...therefore it is obvious to a person of ordinary skill in the art at the time of the invention to modify the clips (of Sander) ..to be made from shape memory metal..." does not have any rational basis in fact. The anchoring members of Sander are joined by a suture (16), which together with the anchors "serve to maintain the tear at close approximation" (Col. 2, lines 64-65). The anchor members "essentially comprise absorbable rods having outwardly projecting barbs...the barbs are provided to anchor the device in the tissue." Col. 2 lines 21-23; Col. 2 lines 39-40. Since the barbed anchor members are provided to anchor the device in the tissue, there exists no motivation to modify the anchor members such that the anchor members would assume an alternate configuration being made of shape memory material. In contrast, the anchor members are "Preferably...constructed of a bioresorbable material." Col. 2, line 30-32. The Office Action §103(a) rejection was made without indication of any motivation to modify Sander or combine the cited

references. Accordingly, neither the knowledge available to those skilled in the art, nor the references themselves suggest modifying Sander's device to include clips made of a shape memory material.

Nonstatutory obviousness-type double patenting rejections

Claims 20 and 22 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 15 of U.S. Patent No. 6,926,730.

Applicants respectfully request withdrawal of the obviousness-type double patenting rejection. Claims 1-22 that were originally filed in this application are identical to original claims 1-22 found in U.S. Serial No. 09/686,004 which is now U.S. Patent 6,926,730. The election of species requirement mailed in the '004 application on 12/17/01 set forth that the application contained "claims directed to the following *patently distinct* species of the claimed invention" and provided that the Species of Figures 1-5 were distinct with respect to the species of Figures 7-8C. In response, Applicants elected to prosecute the species of Figures 1-5 corresponding to claims 1-16, cancelling claims 17-22 (corresponding to Figures 7-8C) and reserved the right to file applications directed to the non-elected subject matter. Claims 17-22 of this application should not now be rejected as "not patentably distinct" from the claims which were elected and prosecuted in the '004 application. The Examiner has advanced that "although the conflicting claims are not identical, they are not patentably distinct from each other". In light of the restriction requirement language of the '004 application stating that the claims are indeed patentably distinct, withdrawal of the rejection is proper and respectfully requested.

AMENDMENT AND RESPONSE UNDER 37 C.F.R. §1.111

Serial No. 10/718,236

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Page 12
Dkt.: P-21779.02

A petition for a three-month extension of time is being made concurrently with this response via the EFS-web. A supplemental information disclosure statement also accompanies this response.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-2546.

Respectfully submitted,

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